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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,350	04/18/2001	Robert M. Scribner	1759.15103-CON	1121
26308	7590	04/26/2004	EXAMINER	
RYAN KROMHOLZ & MANION, S.C. POST OFFICE BOX 26618 MILWAUKEE, WI 53226			KOKABI, AZADEH	
		ART UNIT	PAPER NUMBER	
		3743	15	
DATE MAILED: 04/26/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/837,350	SCRIBNER ET AL.
Examiner	Art Unit	
Azy Kokabi	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 November 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 80-94 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 80-94 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

1. Claim 85 is objected to because of the following informalities: the claim does not end with a period. Appropriate correction is required.

Priority

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as stated in Paper No. 14. In accordance with Paper No. 14, the follow rejections apply.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 80-94 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,607,544. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '544 patent and claims 80-94 of the present application claim a device for compacting cancellous bone having a wall of flexible material, an interior space, a first, second, and third expandable region..

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 80-82, 84-88, and 90-91 are rejected under 35 U.S.C. 102(b) as being anticipated by Reiley et al (WO 95/20362).

In regard to claim 1, Reiley discloses an inflatable device with a flexible, resistant wall (pg. 6, lines 31-35 and pg. 7, lines 1-5), with an interior space (figure 6, # 88), having a proximal end (figure 17(a), #162) and a distal end (figure 17(a), #159). Reiley also discloses an expandable region with its cross-sectional area adjacent the proximal end (figure 18, #166) and a second expandable area with its cross-sectional area adjacent the distal end (figure 18, #170).

The device also contains a third section with its interior cross sectional area located between the

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first and second expandable regions (figure 18, # 172). Reiley discloses that the third section has less interior cross sectional area than the interior cross sectional area of either the first or second expanded sections (figure 18). Reiley also discloses that the third section is surrounded by a mesh, therefore providing for a thicker wall than either the first or second expandable regions (pg. 9, lines 26-35 and pg. 10, lines 1-3 and figure 18, # 170). Reiley teaches that the expandable regions are predetermined (page 6, line 21) and further that the balloons are formed by molding (page 26, line 7).

In regard to claim 81, page 11, lines 4-17 disclose that the inflated balloons have restraints that will create flat surfaces, which will result in a diameter less than a sphere expanded to an equal inflation volume of the balloon. In regard to claim 82, Reiley discloses a balloon that expands outside the bone, having a diameter greater than the normally expanded shape. The balloons occupy 70-90% of the inner volume of the bone so that undue pressure is not exerted on the vertebral body (pg. 11, lines 31-34).

In regard to claim 84, Reiley discloses an expandable region that is "essentially" cylindrical. (See figure 4). In regard to claim 85, see figure 2. In reference to claim 86, Reiley discloses an expandable region that is in an "essentially" cylindrical manner (figure 4 and pg. 8, lines 34-35).

In regard to claim 87, Reiley sets forth the limitations as stated supra in claim 80. When rotating the device 180 degrees, the first balloon will be adjacent the distal end and the second expandable region will be adjacent the proximate end (see figure 18).

In regard to claim 88, figure 18 shows that the first expandable region surrounds the maximum cross sectional area of the first interior space and the second region surrounds the

second maximum cross-sectional region of the interior space. Figure 18 also discloses that the expandable regions of the first and second expandable region are larger than the third expandable region.

In reference to claim 90, Reiley discloses all the limitations as set forth supra in claim 81 and 87. In addition, Reiley shows that the diameter of the third region is smaller than the average of the first and the second expandable regions. (See figure 18). In regard to claim 91, Reiley discloses of a flowable material that sets to a hardened condition in the interior wall (pg. 19, line 30).

7. Claims 80, 84-94 are rejected under 35 U.S.C. 102(b) as being anticipated by Tower et al (U.S. Patent No. 5,352,199).

Tower discloses a balloon catheter having a wall made from a flexible material (see at least column 2, lines 64-66), with an interior space (figure 3), having a proximal end (figure 3) and a distal end (figure 3). Tower also discloses an expandable region with its cross-sectional area adjacent the proximal end and a second expandable area with its cross-sectional area adjacent the distal end (see at least figure 3). The device also contains a third section (#123) with its interior cross sectional area located between the first and second expandable regions. Before the balloon of Tower is fully expanded, the third section has less interior cross sectional area than the interior cross sectional area of either the first or second expanded sections (see figure 3).

The third section, before fully expanded, has less diameter than the first and second regions, therefore having a thicker wall than either the first or second expandable regions. Reiley teaches that the expandable regions are predetermined (column 3, lines 1-10) and further

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that the balloons are formed by blow-molding, which applies heat and pressure (column 3, lines 4-5). The expandable region of the balloon is essentially cylindrical (See figure 5) and the regions expands in a non-spherical manner (see figure 3). A fluid is transferred under pressure for inflation and deflation of the balloon.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 83 and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley et al (WO 95/20362) in view of Reiley et al (WO 98/56301).

As previously, discussed in paragraph 6 above, further Reiley (WO 95/20362) discloses all the limitations as set forth, however Reiley (WO 95/20362) does not teach that the expandable region inside the bone corresponds to the expanded shape outside the bone.

Reiley (WO 98/56301) discloses a balloon inside the bone that corresponds to the shape of a balloon outside the bone (Compare figure 37 A and B). It would have been obvious to one of ordinary skill in the art to modify the device of Reiley (WO 95/20362) with an expandable region inside the bone that corresponds to the expandable region outside the bone, in order to provide confidence for the physician by allowing him to select a structure in an open-air environment.

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10. In reference to claim 89, Reiley (WO 95/20362) does not disclose of a wall made of polyurethane. Reiley (WO 98/56301), however, discloses that the wall of the inflatable device comprises of polyurethane for expansion of the expandable member.

Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Reiley (WO 95/20362) with a wall made of polyurethane in order to provide a durable and flexible material to be inflated inside the cancellous bone.

In reference to new claims 92-94, Reiley does not specify the mode of manufacture of the catheter balloons, however the "Prior Technique for the Manufacture of Balloon" section of the reference refers to patent number 5,163,989 by Campbell, which discloses a molding process of making balloons (see page 3 and 4 of Reiley reference)

Campbell discloses a mold and technique for molding dilation catheters in which the balloons of the catheter is free of parting lines. The technique involves inflating a plastic member of tubular shape so as to press it against the inner molding surface, which is heated. Inflatable devices are molded into the desired size and shape, then cooled and deflated to remove it from the mold. This process is used to obtain a variety of balloons, with different sizes and shapes.

Therefore, it would have been obvious to specify the manufacture of balloons for in patient use in order to form a wide variety of balloons of different sizes and shapes.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Azy Kokabi whose telephone number is (703) 306-4154. The examiner can normally be reached on Monday- Friday, 6:30am to 4:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AK



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